

# **Innovation in the Post-TRIPs Regime in Indian Pharmaceutical Firms: Implications for Pharmaceutical Innovation Model**

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## **1. Introduction**

Innovation is considered to be one of the most important factors in economic competition (Pohlmann, 2005). But innovation does not happen merely by chance. The established literature provides vivid description of technological trajectories, paradigms, innovation paths, and long waves of innovation models (Schumpeter 1947, Nelson and Winter 1977, Dosi 1982 and Rothwell 1992). This literature views innovation as an evolutionary process and asserts that accumulation of skills, experience and technical know-how, whether at the level of firms or of countries, accumulates over time. This means that technology is not something which firms simply choose and buy-in from outside. On the contrary, it is rooted in a specific set of change generating resources (context) or absorptive and innovative capabilities firmly rooted within the structure of technology-oriented firms. In addition, temporal and contextual factors are important in understanding the shaping of an industry within which the critical actors (mainly firms and government) are embedded and perform (Freeman et al 1988). For example factors such as: social requirements, economic status, infrastructure, and policies, may or may not be conducive for innovation in a particular sector or country.

Policies can play a major role in stimulating and supporting the innovation process, notably by shaping the parameters within which choices are made and by agenda setting that targets specific actions for immediate attention. No better example can be cited here than the evolution of Indian pharmaceutical industry under the Indian Patents Act, 1970. This act shaped the reverse engineered based strategies of leading pharmaceutical firms.

In the 1970s there was a vast difference in the technology paradigms and trajectories followed by the firms in India and in the developed countries and the policy influence of the Indian state was evident. Much has changed since the 1990s with the opening of the Indian economy and later with the signing of the TRIPs agreement. Product patents are not new to India, having been established in the early 20th century. However, the context has changed. The major distinctive features of the current era are: a) degree of globalisation; and b) dispersed innovative capacities within the global pharmaceutical industry. Policy changes both at the national and international level such as liberalisation, globalisation and patent harmonisation along with other forces (market and knowledge) have influenced innovation strategies of Indian and multinational firms alike. The implications of these new characteristics on innovation models in the pharmaceutical industry is the focus of this paper. The challenge to firms in this era is to manage the tension between integration of knowledge from different sources and the fragmentation which occurs as a result of needing to outsource rather than fully integrate. The paper links advances in innovation theory with practice (firm level dynamics) by tracing the changing context of innovation and technological developments in Indian pharmaceutical firms in the recent past.

Analysis of recent literature about constantly changing innovation dynamics, policy and firm level strategies in this paper provides deep insights into why and how the process has changed over time. Evolutionary economists emphasize the cumulative and dependent nature of technical and organisational change within firms. The particularities of the way different firms incorporate new technology and new processes needs to be understood in the context of their previous trajectories and their capacity to absorb new knowledge (Cohen and Levinthal 1990). The notion of path dependence has been deployed in the economic history and historical sociology literatures to explain sequences of events related mainly to technological and institutional evolution (David 1994). In this paper the notion is adopted to subdivide sequences of events and self-reinforcing reactive strategies at the level of firms. The findings of this paper illustrate the distinctive competencies and capabilities created by leading Indian pharmaceutical firms during different policy regimes in the past and the reconfiguration of their existing competencies for survival and success in the new innovation-led business environment.

## **2. Structure of the Paper**

The principle objective of this paper is to analyse the interaction between public policy and firm level strategies; and their resultant and cumulative impact on drug innovation models in the Indian pharmaceutical industry. Section 3 presents the research context and the theoretical framework used in this paper. This section also describes the methodology of the study and rationale behind our research design. Section 4 maps the technology and policy co-evolution in the Indian pharmaceutical industry since independence. Providing the necessary historical background, this section explains capacities and capabilities created within the India pharmaceutical industry in the process patent regime and shows how changes in policy regimes have influenced technological choices and trajectories of Indian firms over time. Section 5 identifies the key drivers for research and innovation in the next phase of development for the Indian pharmaceutical industry. Focusing on leading Indian firms, this section investigates their strategies to augment resources (particularly knowledge and skill set) prerequisite for drug discovery and development research in the post-TRIPs regime. Section 6 discusses the transformation of Indian firms as they move from process engineering (working at the lower end) to drug discovery (higher end of pharmaceutical value chain) and assesses the on-going and perspective changes in order to ascertain the direction it might take in the future. The paper concludes with a few final thoughts on the emerging drug innovation models in section 7.

## **3. Research Methodology and Theoretical Framework**

### **3.1 Research Methodology**

A review of firm level case studies in other developing countries like China, Korea and Taiwan (Kim 1997, Lee 2000) suggests that the creative destruction of existing competencies (process innovation in this case) and adoption of new practices (product innovation) is not an easy task and definitely not a one-step-straightforward process. The move has to be gradual and needs to be addressed strategically rather than purely technically. Building further upon this framework, the present paper analyzes the gradual reorientation of Indian firms towards innovation-based R&D. Focusing at firm level, the paper looks at research and innovation strategies that are being devised by the top Indian

firms to attain leadership in the domestic market and carve a niche for themselves in the international market in the post-TRIPs regime. Investigation of these issues in Indian pharmaceutical firms requires detailed information on the firm(s)' history, R&D base, technical capabilities and its own technology policy and strategy. Multiple case studies are used in order to better understand how Indian firms are dealing with the changing policy, knowledge and markets emerging in the post-2005 scenario. Approaches to innovation in the post liberalization and TRIPs era are identified and analysed for their implications for policy-makers, firms and finally for innovation theory. Cases are chosen on the basis of degree of innovativeness in firms. The focus is on leading Indian firms. The multiple case study method allows replication logic with each study confirming or disconfirming inferences from previous ones thereby permitting induction of more reliable strategies.

Changes at the micro level are supplemented by macro analysis. Existing literature has been used to analyse the causes and effects of the legal and policy changes in the last few decades on the growth and evolution of this industry. Literature has been sourced from the annual reports of the Ministry of Science and Technology, the Ministry of Commerce and Industry, Parliamentary reports and reports published by Individual organizations and authors (Ayyangar 1959, NCAER 1984, Watal 2000, Zaveri 2002) and discussions with industry experts. In addition, industry journals, trade journals, and industry associations' publications are also referred to.

### **3.2 Theoretical Framework**

The theoretical framework for this research is based upon the literature of co-evolution of policy and technology, strategic knowledge/innovation management and changing dynamics of innovation process. Focusing on the role of 'firms' in 'making' policy work within a given context, this research examines how policy analysis can be used not only to analyze the policy process, but also to better think about research, innovation and business strategies at firm level.

Strong links between firms, policy and innovation in this particular sector have already been established in the literature (Forbes and Wield 2002, Chaudhuri 2004, Maskus 2003). Many researchers have looked from different angles at how environmental factors such as policy, knowledge and market dynamics can affect firm level strategies (Chaturvedi and Chataway 2006, Halemane 2003, Madanmohan and Krishnan 2003, Fink 2001). Building further upon this work, the present paper synthesizes contributions from three major areas, that is: the notion of technology innovation as an evolutionary and dynamic concept; the notion of firms being based on dynamic capabilities and competencies; and the notion that both endogenous and exogenous factors affect technological trajectories and innovation process at all levels (figure 1). The concepts and theories embedded in figure 1 such as: policy framework acting as a barrier/facilitator to innovation; organizational mechanisms such as strategic alliances and partnerships to bridge knowledge and innovation gaps; and strategies to mitigate cost, time and risk factor inherent in drug innovation (the core of the figure) are utilized while examining the real life phenomena (practice at firms level) in this paper.

#### **4. Innovation: Policy and technology Interactions**

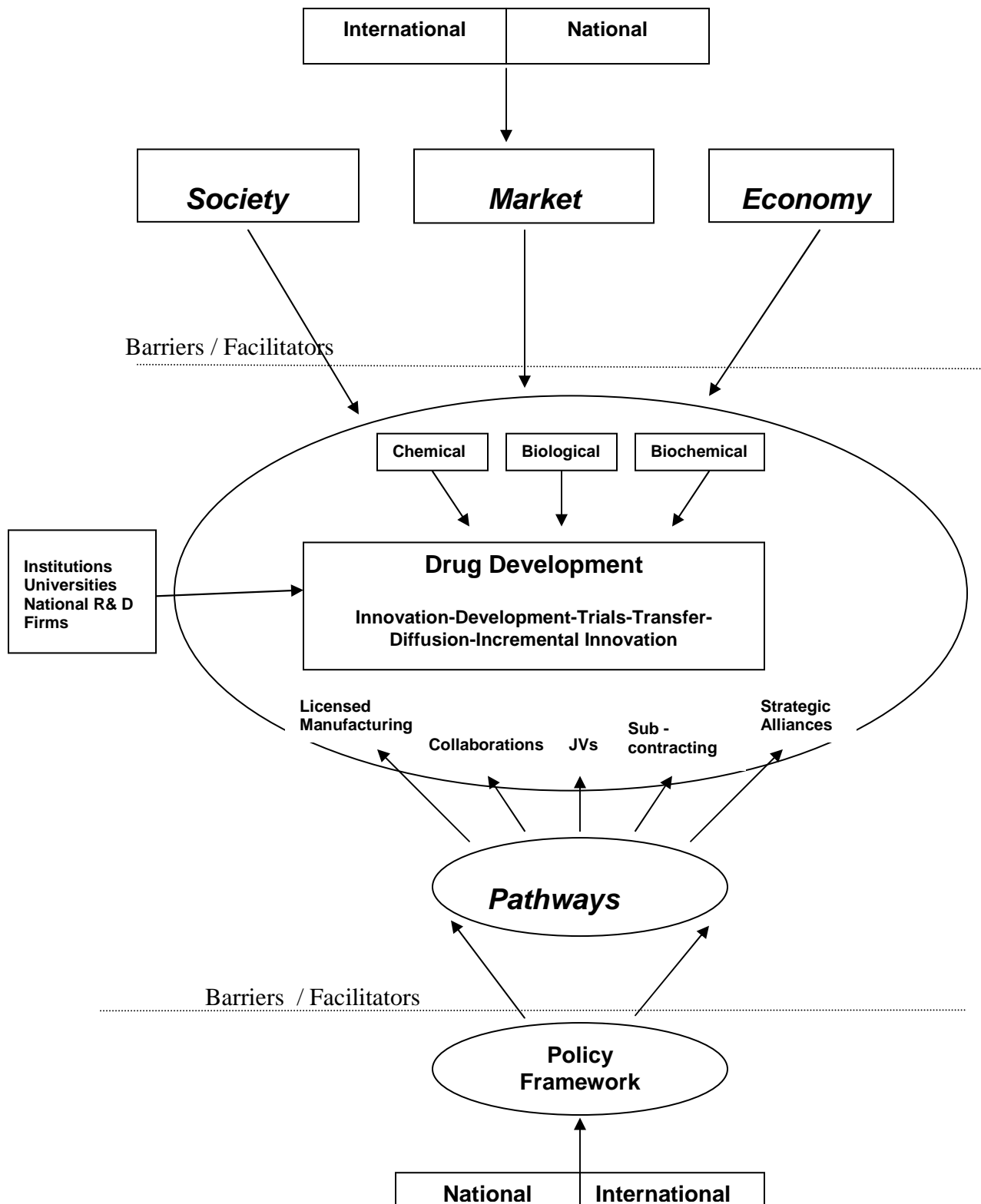
Dosi's definition of technology paradigms and trajectories demonstrate that trajectories can be shaped along the economic and technological trade-offs defined by a paradigm. In this connection policy and development literature suggests that changes at the policy level account in a major way in which technologically dynamic firms and industries emerge and operate in both developing and developed countries (Lall 2003, Maskus 2001, Correa 2000). Schumpeter (1947) with his 'gales of creative destruction' gave a vivid description of the dynamism of innovation and its effects on industrial and world economy. Many authors further contributed to this theory notably Rosenberg (1969), Nelson and Winter (1977), Dosi (1982), and Freeman and Prez (1988). A number of studies have recently looked at the knowledge related policy changes in economic, social and technological development of the developing countries. Lanjouw and Cockburn (2001), Pradhan (2003), and Lalitha (2003) have studied the impact of the introduction of pharmaceutical product patents in India. This literature strongly suggests that the technological growth and development of a country are greatly influenced by the policies that help generate, absorb, diffuse and utilize technological innovations from elsewhere and innovate upon it. Working along the same lines the following section examines the role of policy interventions in promoting local 'technology-generating efforts' and 'production enterprises' in the Indian pharmaceutical industry.

##### **4.1 Historical Perspective and Profile of the Indian Pharmaceutical Industry**

The history of the Indian pharmaceutical sector has been discussed in our previous papers in detail (Chaturvedi and Chataway 2006). The essential features of this history involve the progression from a production and innovation model based on reverse engineering since the 1970s Patents Act to a research-intensive model evolving from the mid 1990s after the signing of the TRIPs agreement.

Before 1970, patent protection served to encourage foreign inventors and foreign R&D under the patents and Design Act, 1911 that India inherited from colonial periods. MNCs patented their inventions in India, but did not produce locally, using the patents to establish protected foreign market in the country (Ayyangar Report 1959, p12). This not only denied the spillovers of technologies developed by MNCs to the local innovation system, but it also did not help developing local technological capabilities. The need for a system that encouraged technology acquisition, transfer, development, diffusion and incremental innovation was obvious. Patent law was used as a tool to establish a more productive innovation system in India; to counteract monopoly abuses by foreign multinationals; and to jumpstart local production.

**Figure 3.1**  
**Conceptual Framework of the Drug Innovation Process**



The Patents Act, 1970, represented a significant change in the legal and technological regime and had an enormous impact on the technological evolution of pharmaceutical industry in India. The 1970s Patents Act propelled Indian firms on a reverse engineering path and spurred the growth of a highly inward looking pharmaceutical firms focusing on the domestic market. The process patent regime allowed the domestic firms to undertake alternative process development. The domestic firms mastered over the process chemistry and operational efficiencies to achieve high yield and productivity (Table 1). The ‘imitative’ follower trajectory differs greatly from the technological trajectories followed by the firms in the US and Europe focusing on research and new drug discovery. Many Indian firms, even though insignificant in size, were able to produce essential drugs like antibiotics at very economical prices. Price sensitive Indian consumers preferred local brands over the exorbitantly priced western brands.

**Table 1**  
**Production of Bulk Drugs and Formulations in India**

Year	Value (in Rs. Crores)		
	Bulk drugs	Formulations	Total
1975-76	130	560	690
1980-81	240	1,240	1,440
1990-91	730	3,840	4,570
1994-95	1,518	7,935	9,453
1998-99	3,148	13,878	17,026

Source: Department of Chemicals and Fertilizers, Various Annual Reports.

The dynamics between local and western MNCs changed drastically from 1970s to 1990s. The overall policy, technology and market environment lowered the entry barriers and encouraged a large number of smaller enterprises to enter the market and compete with the MNCs in the domestic market. This resulted in disinvestment by MNCs that decided to exit the market. The market shares changed tremendously, bearing witness to the downfall of the western multinationals from the mid 1970s (Table 2). By the mid 1990s the dominance and monopoly of MNCs was completely wiped out by the local firms.

**Table 2**  
**Changes in the Structural Composition of the Indian Pharmaceutical Industry**

Nature of Firm	1970	1982	1993
Western Multinationals	80	50	39
Indian Public Sector	10	2	1
Indian Private Sector	10	48	60

Source: Redwood, 1994.

The policy environment during 1980s provided an opportunity to learn while doing by eliminating fear of competition from more established and technologically advanced MNCs (Felker 1997). The technology progress during this period was mainly driven by ‘technology-followers’ approach and ‘low-cost innovations and products’ goal. From an

Indian perspective, lack of intellectual property rights laid the foundation for a strong domestic industry in the initial formative years and later gradual liberalization in 1990s enhanced competition and concern for quality and innovation.

The fresh lease of reforms (liberalization) added pace to technological advancement. Much new technology was still imported but some leading firms started investing more in in-house R&D as a move to build a proprietary technological base (case-studies). “There were even more successful attempts to produce products better tailored than MNC drugs for the Indian market” (Smith 2000, p14). Driven by the large global generic markets of the developed world, Indian firms gradually created capability for generics R&D. Through the late 1980s and early 1990s, Indian firms grew increasingly sophisticated in their management and their strategy, focusing on backward integration, fragmentation and enhancing plant capacities. The reforms not only enabled the emergence of a competitive domestic industry but also set the foundation for generic drug production for international markets.

After more than a decade of liberalization the macro-review of technological changes in India does not show any dramatic changes but the level of the individual firm (micro-view) points to a more radical change in basic technology as well as in managing advanced technology. Many pharmaceutical firms like Cipla, Alembic, Cadila, Torrent and Lupin improved their manufacturing efficiency and established large production facilities. Sun, Zydus, Dabur, Ranbaxy and Wockhardt restructured and shifted their technology focus, product basket and market focus. Ranbaxy, Dr. Reddy’s, Sun, Lupin, Torrent and Wockhardt substantially increased their in-house R&D investments and implemented new approaches to drug/product development. Most technological changes were driven by competition in the liberalized market. Changes were not entirely due to liberalization; some ambitious and visionary firms had started taking technological initiatives even before liberalization nonetheless, liberalization did set the pace.

Overall, competition with foreign firms and foreign products in the domestic market, exposure to the global markets, and realisation of future regulatory changes provided much needed innovative orientation to the imitative research in the early 1990s and tremendous boost to the production range and capacities. The number of brands in the domestic market with varying levels of credibility, vintages and therapeutic effectiveness, are over 6,500 in 77 therapeutic segments. The investments which stood at Rs. 2250 million in 1973, rose to Rs. 6000 million by 1982, which further increased to Rs. 18400 and Rs. 45000 million in 1997-98 and 2002-2003 (Nauriyal 2006). The average growth in the last few years has been about 12% (Ganguli 2003). Table 3 summarizes the growth and progress of the Indian pharmaceutical industry just before TRIPs implementation.

**Table 3**  
**Indian Pharmaceutical Industry: Growth Indicators (in Rs. Million)**

Particulars	1965-66	1980-81	1997-98	1999-00	2002-01	2002-03
Capital Investment	1,400	5,000	18,400	25,000	29,000	45,000
Production	1,680	14,400	146,910	197,370	228,870	392,547
Formulation	1,500	12,000	120,680	159,600	183,540	238,659
Bulk drugs	180	2,400	26,230	37,770	45,330	63,908
Export	30.5	464	53,530	72,300	87,340	128,260
Import	82	1125	28,680	16,160	29,800	28,650
R&D Expenditure	30	147.5	2,200	3,200	3,700	6,600

Source: Nauriyal, 2006

### **5. New Patent Regime (TRIPs) and Challenges Ahead**

TRIPs marked the turning point of India's policy regime towards the world. The 1970s Patents Act that facilitated the extraordinary growth of the domestic industry has been totally reversed with the signing of the TRIPs agreement in 1995. The TRIPs agreement requires WTO members to include 'recognition of product patents for pharmaceuticals with 20 year terms' in their domestic patent laws. Besides, importation of patented products once again satisfies the 'working' requirement of a patent (Pharma Policy 2002). TRIPs has challenged both the government and local firms in many ways. At the national level, these challenges demand new initiatives beyond those enumerated in the Drug Policy 1985 (modified in 1994), so that policy inputs are directed more towards promoting accelerated growth of the industry and towards making it more internationally competitive. The Drug Policy 2002 has been framed against this backdrop. At firm level enhanced R&D focus is unarguable. The broadening of the IPR regime shifts the incentives for innovation creation from the second innovator to the first innovator (Ramani et al 2005). As a consequence major changes have occurred at the industry and firm level during the transition period (1995-2005). The key observations and our research findings are summarized below.

#### **5.1 Innovation Strategies in the Post-TRIPs Regime**

As is evident from our discussions in section 4, the knowledge base and capabilities of Indian pharmaceutical industry is firmly rooted in reverse engineering based R&D. Core-competencies at the firm level created in the past however, vary from one to another firm and each firm has therefore devised a different strategy for itself in the post-TRIPs regime. Firms like Ranbaxy, Dr. Reddy's, Dabur, Sun, Wockhardt, and Torrent are seriously pursuing new drug discovery programs now. Our research suggests that these are the firms, generally, that have invested more in the R content of R&D and have gradually moved away from reverse engineering. Other firms like Cipla, Lupin, Cadila and NPIL have invested more in the D content and have strengthened their infrastructure and financial position through process efficiencies, economies of scale and large product baskets rather than research. These firms are of the opinion that technology needs to be fostered gradually and hence are taking a slightly different route to drug discovery. Within these two very broad categories there is further differentiation. Nonetheless R&D does seem to be judged as essential in the long term by all firms. State of the art R&D



facilities equipped with sophisticated instruments, equipments and skills are considered an absolute essential part of corporate strategy and accordingly investments are being made (company interviews and visits to research parks). The enhanced levels of key activities are discussed below:

### **Enhanced R&D Investments**

Changes in patent law under TRIPs obligation, preventing the reverse engineering of patented molecules has forced Indian firms to enhance their R&D efforts and investments. Our case studies suggest that from about 2 per cent of total sales around 3-4 years ago, the average R&D expenditures of the leading research based domestic firms has gone up to around 5-6 per cent in 2003-2004 (Table 4). Among these companies Ranbaxy, Dr. Reddy's, Cipla, Wockhardt, Torrent, Sun, Lupin and Nicholas Piramal are prominent. Dr. Reddy's R&D expenditure increased from 7 per cent in 2002-03 to 10 per cent in 2003-04 and is slated to increase further in future.

**Table 4**  
**R&D Investments in Selected Indian Pharmaceutical firms**

Company	R&D Spend as % of Sales					
	1999-00	2000-01	2001-02	2002-03	2003-04	2004-05*
Ranbaxy	3.6	4.2	4.0	5.0 - 5.5	6.3	7.0 - 8.0
Dr. Reddy's	2.7	3.5	4.0 - 4.5	6.8	9.9	12.9
Cipla	3.5	3.5	4.0 - 4.5	4.5 - 4.8	4.8 - 5.0	5.0 - 5.5
NPIL	2.0	2.0	2.0	2.0	4.0	5.0
Sun	4.0	4.0	4.0	7.0	10.0	10.0 - 12.0
Lupin	1.7	2.0	2.0	3.0	3.0 - 3.5	8.0
Dabur	-	-	-	-	8.0 - 9.0	8.0 - 9.0
Cadila Pharma	1.0 - 2.0	1.0 - 2.0	1.0 - 2.0	2.0	2.0 - 3.0	3.0 - 4.0

Sources: Compiled by Chaturvedi from various sources (Company interviews, Annual Reports, Journal Articles and Press releases. \* represents projected investments.

At the macro-level, the total R&D expenditure, which was only Rs. 3 crores in 1965-66, reached an impressive Rs. 140 crores in 1995, a significant year, when the WTO and IPR protection came into being. With the increasing realization that copying will no longer be permissible after 2005, R&D investments have gained serious momentum since the late 1990s (Mashelkar 2001).

### **Enhanced Patent Filings**

The number of patents filed and granted in a particular sector indicates the level of inventive activity and R&D capabilities of a country in that sector. Two Indian entities, CSIR (Council of Scientific and Industrial Research) and Ranbaxy, find mention in the top ten list of World Intellectual Property Organization (WIPO)'s list of 2002. Patent applications by industry during 1995-2000 indicate that pharmaceuticals ranks highest with 396 applications). India filed more than 112 ANDAs (abbreviated new drug applications) in 2003 and 392 in 2002. India's share of ANDA filings has been rising consistently and was around 23% in 2003 (IPR, various issues).

Firms have used multiple approaches to create intellectual property such as filing for Indian patents, international patents, ANDAs, and DMFs (drug master files). Firms like Dr. Reddy's and Ranbaxy have made use of first-to-file and Para-IV filings as well. However, other firms like Cipla, Cadila, Lupin, Sun and Zydus have opted for DMFs to gain cheaper and faster entry to regulated markets (Table 5). Indian firms accounted for over 30% of the DMFs filed in the USA in 2003 (Chaturvedi and Chataway 2006). It remained in first position with 126 DMFs in 2003 alone (India Folio 2004). This indicates not only the present level of patenting activity in Indian pharma but commitment (pipeline) for the future as well.

**Table 5**  
**Patent Filings by Indian Pharmaceutical Majors**

Company	Total No. of Patents	ANDAs				DMFs	
		Filed	Para IV	First to File	Target	Filed	Target
Ranbaxy	489	127 (92*)	22	12	15-20	48 (2003)	15-20
DRL	213	42 (12*)	24	9	15-18	100 (56 in 2003)	20
Cipla	NA	15 (35**)	15	5	15-20	53 (in 2003)	20
Sun	132	13(2*)	0	0	8-10	22	8-10
Lupin	162	13(5*)	0	0	12-16	82 (21 in 2003)	20-25

Source: Compiled by Chaturvedi from various sources. \*represents approved, \*\* represents to be filed in 2004-2005.

### **Enhanced Collaborations for Research and Development**

Indian firms have collaborated aggressively with premium technology and research institutions in the recent past with the main objectives of integrating new knowledge and skills from external sources and for changing their market image (research driven). Ranbaxy, Cipla, Lupin, Cadila pharmaceuticals, Dabur, Zydus, Wockhardt, Sun and Torrent are all involved in such alliances. These firms have acquired assets and formed alliances with the firms based in other countries to expand their international presence on one hand and have collaborated with premium technology institutes to strengthen their technology base. Acquiring firms with existing innovative product lines or products in the advanced stage of development is favored by the leaders. Coordinating and redeploying internal and external sources appears to be the key strategy to address the rapidly changing technology and business environments.

Case analysis in this paper suggests that the focus of collaborations in 1990s was on integrating brands, manufacturing capacities, and marketing and distribution networks. Vertical integration achieved new heights during market liberalization in 1990s. Ranbaxy, Nicholas Piramal, Sun, Lupin, Cipla all expanded their manufacturing operations, marketing and distribution networks, product portfolios and brands through backward and forward integration. Ranbaxy bought 30 per cent stake in Vorin Laboratories in order to gain control over a key raw material and intermediate supplier

for its famous product Ciprofloxacin. Sun Pharma utilized acquisitions for its organic and inorganic growth. Its acquisition of MJ Pharma and Gujarat Lyka was a part of its multi-media strategy while integrating TDPL is an entry strategy into specialties areas like oncology, gynaecology and pain management. However, with the signing of TRIPs in 1995 and changes in the patent laws, the focus of collaborations has shifted to research and development. The emphasis is on knowledge and technology integration rather than the critical mass and economies of scale. Many top Indian firms have pursued collaborations with international drug companies to access technology and knowledge vigorously in last 5 years or so. For example, Ranbaxy with Eli Lilly and Gist Brocades, Dr. Reddy's with Novartis and Novo Nordisk, Lupin with Merck Generics and Wyeth Lederle, Torrent pharmaceuticals with Novo Nordisk of Denmark and Sanofi of France and Cadila Pharmaceuticals with M M Schwabe, USA. Nicholas Piramal has acquired R&D facilities from international leaders such as Hoechst, Boehringer Mannheim and Roche in order to augment its knowledge base. Sun Pharma's acquisition of USFDA approved Caraco Pharma Labs and Knoll's bulk laboratory was also motivated by the firm's technological strengthening strategy.

Recent trends suggest a change in the mindset of Indian entrepreneurs and change in the motives behind strategic alliances pursued by the Indian firms. India firms have ambitious plans to launch their own new chemical entities (NCEs) and new drugs and have charted R&D strategies to build and fuel their drug discovery pipeline albeit with a different time-frame (short, medium and long).

## **5.2 Knowledge and Innovation Management in the Post-TRIPs Regime**

The 'dynamic capabilities framework' by Teece et al (1997) directly addresses a firm's ability to strategically integrate, build and reconfigure internal and external competencies to address rapidly changing environments. The approach emphasizes firm-specific capabilities, assets, paths and strategies. The capabilities here do not represent technological capabilities alone but also management capabilities and difficult-to-imitate combinations of organizational, functional and technological skills. Elements of this approach are evident in the overall corporate strategy of our cases. Various initiatives have been taken by firms to enhance and accelerate research and innovation in drug development. For example, licensing product patents from patent holders; acquiring their own patents through indigenous R&D; and integrating new knowledge and resources from external sources. Consortia approaches, involving universities and national laboratories within and across boundaries for new drug discovery, are increasingly finding favor with technology intensive firms (Sakakibara & Dodgson 2003, Bower and Sulej 2005).

Chiesa and Toletti (2004) in their recent study of biotechnology sector highlighted the role of strategic alliances in the development of R&D capability, the rate and quality of innovation, knowledge transfer; and organisational learning. Resonating the same Indian firms also assert that innovative capacity is a determinant key factor of a firm's competitive standing in global markets and strategic alliances are key to achieve knowledge advantages. Within this approach 'cooperate' rather than 'compete' is the mantra for success. Ranbaxy teaming up with its otherwise local competitor firm Cipla

for marketing Carvedilo is a case in point. Firms are not opting for aggressive competition with domestic firms or with the established international players in the near future, though some of the visionary firms in the top league with strong financial muscle and better infrastructure may use a combination of cooperation and competition. The idea is to acquire, assimilate, innovate and then compete (company interview). Strategic outsourcing and in-sourcing has assumed an increasingly important role in the operations of established as well as emerging pharmaceutical firms in India.

### **Subcontracting**

Large scale subcontracting of research is a relatively recent phenomenon in the pharmaceutical industry. There is an increasing recognition in Indian pharmaceutical firms that one company's peripheral technologies are on other's core activities, and that it makes sense to source such technologies externally rather than to incur the risks, costs and most importantly of all, time-scale associated with the in-house development. Earlier, subcontracting in pharmaceuticals was mainly restricted to intermediate or APIs suppliers. Now as the firms are moving up the higher value chain and competing to launch new drugs, subcontracting for research, clinical trials, custom synthesis, marketing and sales support is gaining popularity. Increasingly, superior capabilities are being developed by the companies that concentrate on single element of drug development. Organisations like Siro-Clinpharm-a group company of Bharat Serums and Vaccines, Syngene-a subsidiary of Biocon India, Wellquest-a subsidiary of Nicholas Piramal, Aurigene-a sister concern of Dr. Reddy's and Clingene International-a group company of Biocon India are offering contract research services in India. These organisations provide research services all along the discovery chain including structure-guided generation of hit molecules from novel targets, validated targets, and drug-like molecules besides conducting clinical trials. Vimta Labs, Lambda Therapeutic Research, Synchron Research Services, ClinInvent Research, iGATE Clinical Research International, Genotex International, and ClinTec International are the other major clinical research organizations operating in India. Clinical trials are the most expensive and time consuming stage of the drug development and innovation process. Our case studies indicate that Indian firms possess resources that should allow the industry to offer high end value services at a very competitive cost. Regulatory system at operational level, however needs to brace itself to be in sync with the ambitions and strategies of these firms.

Western multinationals are vigorously scouting for clinical development services and the painstaking chemical synthesis work for early drug development in India. They are also shopping for promising new treatments that may emerge from India's own drug discovery efforts. Backed by the recent government notification amending Schedule Y, multinationals like Pfizer, Eli Lilly, GlaxoSmithKline and Aventis have kick started simultaneous and stand-alone clinical trials in various therapeutic segments. Eli Lilly has over 17 large and small clinical research projects running in 40 hospitals across India, while GSK Plc has started seven simultaneous clinical trials of its vaccines and drugs. Global consultancy major McKinsey (2003) estimates that by 2010, global pharma majors would invest \$1-1.5 billion in the Indian market. Clinical research constitutes a major part of drug innovation process. Policy impact (the Schedule Y booster shot and

TRIPs implementation) at operational level (firms) is clearly visible which heralds changes in the innovation models.

### **Technology Licensing**

Indian firms (Ranbaxy, Cipla, Dr. Reddy's, Nicholas Piramal) realise that it will be difficult for them to commercialise their discoveries on an international basis on their own and hence are getting into licensing deals and strategic alliances with international companies. The cases under study suggest a change in the traditional technology development and commercialization practices (where most of the innovations have emerged from in-house R&D efforts) to more open and participative approaches. Dr. Reddy's and Ranbaxy have licensed-out their molecules in order to gain advantages related to speed to market, early launch and cost savings. Dr. Reddy licensed two of its compounds to Novo Nordisk for Phase II clinical trials and further development. Besides enabling Dr. Reddy's to take its molecule to the market faster, the strategy has helped the firm to strengthen its learning about discovery, development and commercialisation of NCEs. The strategic integrated discovery approach has helped meld talent and skills throughout the organization (company interview).

Similarly Ranbaxy licensed-out the development of a unique once a day formulation of Ciprofloxacin to Bayer AG- that has been a breakthrough success for the company. Cipla has been involved in intensive technology buying and selling worldwide. Cipla has licensing agreements with Canadian generics manufacturer Novopharm; with MCPC of Saudi Arabia for formulations; with Cipharm in Ivory Coast for formulations; with Geneva Pharma in the US, which is now a part of Novartis for generics; and with a host of manufacturers of antibiotics, anti-cancer and other life saving drugs in China. Thus a mix of licensing in and out is being used by Indian firms to acquire knowledge and expertise from external sources.

Thus on one hand Indian firms are providing high value services to multinational giants and on the other hand sourcing the missing links of in-house drug innovation from them. The combo strategies of exploiting the 'existing' and developing 'new' capabilities makes perfect business sense and is increasingly being practised by the Indian leaders (KPMG 2003, Merchant 2004, Company interviews). In this version of advanced catch up model, firms (in developing countries) are increasingly able to challenge leading firms in developed countries (Hobday 2002). The study of these emerging patterns not only indicates deviation from the past practices but also guides current and future processes of innovation as imitator firms increasingly reach the frontier of technology, perform R&D and compete in the global market place.

### **6. Implications for Innovation Theory**

Since the advent of the embryonic model almost a century ago, innovation process has gradually and continuously evolved over time in line with technology development and environmental change (Park 2006, Nieto 2002, Amidon 1996, Rothwell 1994). Many authors like Nelson 1982, Freeman 1997, Rothwell 1992, and Mytelka 2003 in their study of innovation systems, have introduced a multitude of factors to account for the enhanced complexities and changes in the process over a period of time. A review of Rothwell's

five generations models confirms that each generation had a different model and every new (generation) model had some new dimensions and perspective added to the previous (generation) model. This interpretation demonstrates changes in the driving forces and critical factors for success over time and therefore changes in the innovation models. Working along the same lines, finding of this research strongly indicates that the relative importance of forces (science, technology, policy, market, and economics) driving innovation vary considerably during different phases of maturity. It suggests that one or several of these forces became in a general way the most dominant corporate strategy focus - science in the early 40s; process technology (push) in the 70s; manufacturing in the 80s; marketing and distribution in the 90s; and research and development from 2000 onwards. This indicates that the intensities of driving forces are time dependent as are the synergies among them. In fact, various metaphors in the study of knowledge-based innovation systems can be considered as appreciations of a complex dynamics from different perspectives which keep changing with time.

In India, since the 1990s the situation appears to have a broad combination of central strategic themes like mergers and acquisitions, technological accumulation, inter-firm collaborations, and product and manufacturing integration (Rothwell's SIN model). The situation has been further aggravated by knowledge-base expansion and global strategies themes (contract research, contract manufacturing, custom synthesis) coming to the fore. Our case studies suggest knowledge and policy (which are now more global) as the major driving forces of the present times. Synergy between these two forces exerts a strong influence on firm innovation approaches which in turn has implications for theory of innovation.

Co-evolution of the technology (genomics, proteomics, new technology platforms) and policy developments in the 20th century clearly demonstrates changes in the innovation and wealth creation approaches (strategies) at firm level. Rapidly changing technology and policy environments have transformed the majority of wealth-creating work from "physically-based" (labour and capital intensive) to "knowledge-based". As our case studies demonstrate the major comparative advantage that a company enjoys in the present context, hinges on its process of innovation that essentially involves combining market and technology know-how with the creative prowess of new knowledge. Knowledge is at the heart of corporate strategy and innovation model. Virtually all other resources depend upon some degree of knowledge exploitation for their value. Firms are exploiting knowledge in order to build innovative capabilities and competencies and to exploit new markets (geographical as well as technical) and opportunities. Modern literature on innovation management further confirms knowledge as the most critical resource and asserts that in the new perspective, knowledge management ought to be considered as a strategic necessity for firms (Park and Kim 2006, Jones 2002, Pavitt 2002, Malerba and Orsenigo 2001). These knowledge-led-innovations are a strong invitation to redefine the basic innovation model and to further analyze the contractual and organizational mechanisms that enhance the efficiency of innovation in the present context.

## **6.1 Changing Innovation Dynamics**

Innovation theories and models have since evolved from simple linear sequential models to what Rothwell (1992) refers to as third, fourth and finally fifth generation (System Integration Networking) model. Rothwell's fourth and fifth generation innovation models are based on research observations during 1980s and 1990s, highlighting an increase in corporate alliances, partnerships, R&D collaborations and joint ventures. These models placed additional emphasis on the high degree of cross-functional integration within firms, as well as external integration of capabilities from other firms, suppliers, customers, government and academia. The emphasis throughout is on internal integration.

Until the mid 1990s, the fourth generation model represented a close approximation to actual global best practice. The advent of biotechnologies, computing technologies, multidisciplinary R&D and new policies, however, added many more dimensions to this model. In response to the changing environment and context, a new fifth generation model emerged placing increased emphasis on the strategic integration for co-development of new products, collaborative research, co-marketing, corporate flexibility and focus on standards services and other non-priced factors. Thus despite enhanced merger and acquisition activity, innovation in the pharmaceutical industry has become increasingly diffuse across firms in the recent past.

The global literature on pharmaceutical research also suggests that the corporate structure of the industry is changing rapidly as new companies proliferate and large companies consolidate to deal with the growing cost and complexity of new drug development. Simultaneously, and partly as a result of these changes, new centres of excellence are identified around the globe. India, Brazil, China, and Mexico are beginning to appear on the global pharmaceutical map. This future map of global pharmaceutical R&D and innovation appears to be significantly more fragmented than the present one. India is becoming an integral part of the global pharma value chain, as large global pharma companies continue to increase their sourcing of APIs, offshoring of clinical development and partnering with domestic companies for new product development and marketing in India. Today new business led-R&D models are more obvious than was previously predicted.

Focus on the business, science and economics of NCE discovery wherein clinical research in India promises major contribution exerts a strong influence on firm level innovation approaches at national as well as at international level. The R&D function in business firms world over has shifted focus to the strategic integration of R&D effort with overall business goal. These shifts reflect the increasing complexity and maturity in which companies are tackling the management of their knowledge/technology, products and markets. Knowledge integration from external sources on one hand and fragmentation of the drug innovation process for exploiting time, cost and market advantages on the other, represent extreme complexity of the contemporary innovation model. Striking the right balance between 'integration' and 'fragmentation' and managing the tension between the two is a crucial task faced by firms across the globe. Outsourcing, co-development deals, and in and out-licensing are common features in

pharmaceuticals. Discovery alliances between Indian and international companies like AstraZeneca/Torrent, Lilly/Jubilant, GSK/Wyeth and clinical trials alliances from Avalon, Triesta, Merck KGaA and MSD Pharmaceuticals bring testimony to the complexities and changes in the drug innovation process/model.

## **6.2 ‘Innovation’ in Innovation Models**

The discussion in this paper has provided enough evidence to corroborate that the debate on innovation has shifted focus from individual outputs to the ‘mechanisms’ for producing these outputs. During this transition the realisation has grown that knowledge creation and its commercialization requires participation of many organisations and individuals. Weakness of one organization can be overcome by partnering with the leaders (organizations) or experts in that area.

The resulting system constitutes a dense and complex network of interconnected parts which in literature signifies an intensification of linkages across the innovation system. The major actors in this system - the private sector, the public sector, government departments and ministries, universities and technology institutes-relate to each other in complex ways. In the Indian pharmaceutical sector the more innovative elements of the national innovation system are largely centered in the private firms. These firms are acquiring and integrating knowledge, information, technology, brands and markets from external sources in addition to enhancing their in-house efforts.

The sole focus on strategic integration and in-house R&D of the 1990s is slowly but surely changing to contract research and outsourcing. Most of the firms interviewed for this research are of the view that integrating every task within the firm does not make much economical sense or gain even time advantages. The idea of developing core competencies in few and capacities to absorb the rest from outside is increasingly being practiced in most of the firms. Rothwell’s 5th generation models emphasized the need for internalisation to a very high degree. The current trends, however, indicate a combination of integration and fragmentation. The reasons may vary across the countries depending upon their level of maturity and size but in general pharmaceutical firms are adopting the decoupling model. In the developed part of the world low R&D productivity, high R&D costs and sustainability of such high expenditures for long term are cited as the main reasons whereas in India lack of financial, infrastructural and technological resources for taking the new molecules to the market place is the main reason.

Although Rothwell’s 5th generation model is quite advanced and explains iteration within an organisation, it falls short in explaining external networks. Thus in the current form Rothwell’s model is not appropriate for dealing with new forms of innovation and requires updating. New models of successful participation between large integrated players and niche players is strongly emerging both at national and international level: niche players that optimize a part of drug discovery process to provide services to integrated companies; and large players that control the overall development but source best services available both internally and externally. Emerging trends indicate that although some large firms may assess the external options and continue to integrate vertically, a majority of firms will choose to narrow their activities to one niche or at the



most a few and outsource the rest. The firm level analysis observed contracting rather than integrating to be the optimal strategy.

## **7. Conclusion**

Collective analysis of selected cases in this paper implies that Indian firms are adapting to the changing environments by making midway strategic corrections and are continuously integrating new parallel streams in the mainstream of corporate strategy. R&D is recognized as the 'survival kit' in the post-TRIPs scenario and building the science base for innovations is deemed necessary for long-term growth by Indian leaders. Most firms have reconfigured their research on short, medium and long term bases. Firms have devised strategies to maintain a steady cash flow tapping the large US generics market and by leveraging their manufacturing and clinical research strengths/services in the short term. In the medium term, they intend to move up the value chain through NDDS which can be patented and finally in the long term launch their own molecules. The paper observed that Indian firms are investing in R&D not only for new drug discovery but for developing capabilities to assimilate and exploit knowledge available externally; and for positioning themselves as a partner of choice for technology savvy national and multinational firms. The indigenous capability development is viewed as a powerful strategic tool to exchange and acquire new and emerging technologies from external sources.

On the innovation process front, rapid changes in technologies and external environment beyond the control of a firm are revolutionizing the drug discovery process and approach to innovation. Large firms are strategizing to cater to advanced, regulated and diversified markets, but they are not trying to create in-house expertise for all. Instead they are spreading their research and knowledge networks. As the pharmaceutical innovation model evolves further and external providers develop superior skills and knowledge, the integrated companies are being transformed through a complex web of partnerships and alliances. The fifth generation integration model appears to be evolving into a new decoupling model. The findings of this analysis suggest that in the new policy and knowledge intensive environment, one company can identify a new compound, another can process and develop it, a third can carry it through clinical development and still fourth can launch it.

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